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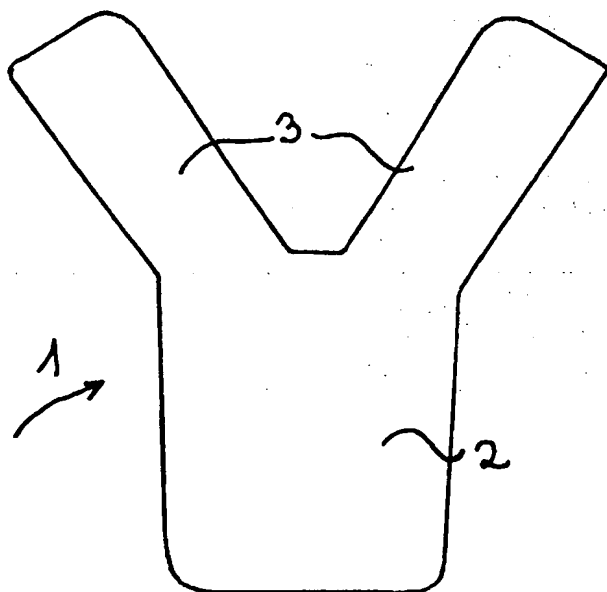
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*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: CORRECTIVE MESH FOR BODY TISSUES

(57) Abstract: A corrective mesh for body tissues comprises a main body (2, 12) provided with at least a pair of upper lateral fins (3, 13) adapted to be introduced along with the main body (2, 12) into appropriate body cavities.



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**"Corrective mesh for body tissues"**

The present invention relates to a corrective mesh for body tissues.

In a more precise manner, the present invention concerns a corrective mesh and its application into human body in order to solve particularly the problems associated to female incontinence.

While excluding the problems due to the incontinence from strain, it is possible that a women pathology, which is relative to the defects of pelvic statics and results in above mentioned problems of urinary incontinence, develops in time.

Such a pathology is clearly more frequent in women who passed the menopause period, and by considering that, owing to the extension of average life duration a longer and longer part of their life will be spent after menopause, the clinical importance of the cited pathology can be understood.

Particularly the main reason of such an incontinence is the descensus of front vaginal wall or cystocele.

In order to repair cystocele the vaginal approach, which generates from the defects of endopelvic fascia and of ligamentous structures, is now based on medialization techniques of the pubis-cervix fascia or on front colporaphe or association techniques with musculo-tendinous structures.

The tissue, which is collapsed, is virtually subjected to further strains or tensions which can furthermore worsen the situation as it will be well described below.

As a matter of fact, the techniques used today while solving the cited problems, have the following drawbacks.

The prior art surgery methodology has take place in complete anaesthesia with consequent complications related to the procedure and patient tolerability.

The postoperative course is not short and painless for the patient and furthermore the stresses, which the collapsed tissue is subjected to, can determine further collapses or strength unbalance on the other vaginal segments.

Moreover during the long distance "follow up" the percentage of relapses by using such techniques, varies from 3% to 70%, as it is indicated in last decade's literature.

The object of the present invention is to avoid such prior art drawbacks.

Hence the invention aims to a corrective mesh for body tissues of easy conception and application, which by its correct positioning substitutes the collapsed body tissue in its functionality.

Briefly, according to the invention a corrective mesh for body tissues has  
5 been obtained which comprises a main body provided with at least a pair of upper lateral fins adapted to be introduced along with the main body in appropriate body cavities.

The corrective mesh for body tissues according to the invention is characterized by the features recited in claim 1.

10 The use of the present mesh on patients with different anatomic characteristics and for several pathologies is possible because said main body and said upper-lateral fins are substantially rectangular shaped with rounded vertexes.

The mesh according to the present invention is perfectly bio-compatible and  
15 avoids any kind of rejection problem because said mesh is made of monofilament polypropylene.

The placement of the present corrective mesh is especially easy because the mesh is completely wrapped by a nylon sheath.

Further characteristics, advantages and details of the corrective mesh for  
20 body tissues according to the invention, will be more evident from the following detailed description making reference to the attached drawings wherein preferred embodiments are shown in a non limitative and illustrative way.

Figure 1 is a top view of a corrective mesh for body tissues according to the invention.

25 Figure 2 is a top view of a second embodiment of the corrective mesh according to the invention.

Figure 3 is a top view of a third embodiment of the present corrective mesh.

Figure 4 is a top view of a further embodiment of the mesh according to the invention.

30 Figure 5 is a top view of an embodiment of the present corrective mesh having a greater covering area.

Figure 6 is a top view of a further embodiment of the mesh according to the invention.

With reference to the Figures 1, 2, 3 the corrective mesh 1 for body tissues according to the invention comprises, independently from the final embodiment, a central body 2 which is substantially rectangular shaped with rounded vertexes. The length ratio between a pair of parallel sides can change according to the model, because for every patient a dimensional model which is more consistent with their anatomic characteristics is tried to be obtained.

From one or more of the bases of the central body 2 two lateral or upper lateral fins 3 divert, which are rectangular shaped with rounded vertexes as well and have an average variable length from about one to about five times the maximum length of said main body 2, achieving further variation of the typologies of obtainable models.

The material used for carrying out the mesh according the present invention must be of course bio-compatible in order to avoid any kind of rejection and preferably it consists of monofilament propylene.

The total sizes of the complete mesh, as already cited, can be very different, e.g. models can have a central body 2 of 5x4 cm size with fins of 4 cm in length or models of 8x9 cm size as a whole or long models of 40 cm in length and 10mm in width.

Such different typologies of models obtainable have not only the functionality of better adaptability as shown before, but also of versatility in the possibility of treating different pathologies.

With reference to Figure 4, for instance, a mesh 11 has a central body 12 of rectangular shape whose size of the small sides is about half or a third part of the size of the long sides.

From one of these long sides a pair of upper lateral rectangular fins 13 diverts. These fins are about four times longer than the size of the long side of the central body 12.

Such an embodiment, as it is easily noted, is nothing but a dimensional variant of the present invention. It is also particularly advantageous in the male abdominal surgery in order to avoid the pathology concerning prolapse of the rectum.

With particular reference to Figure 5, a corrective mesh 21 is then shown especially adapted to be used on wide covering areas. It has a generally circular shaped main body 22 with a notch 25 preferably of rectangular shape in order to

facilitate the positioning of the mesh 21 with respect of the urethra near the connection of two upper lateral fins 23 rectangular shaped with rounded vertexes.

A further embodiment of the present mesh is clearly illustrated in Figure 6. A bulge 4 is provided in the mesh on the main body 2 near the connection of fins 3, said bulge 4 being preferably rectangular shaped. The corrective mesh 1 so  
5 obtained allows an easy connection to the urethra when it is desired.

A nylon sheath (not illustrated in the drawings) wrapping the whole mesh 1, 11, 21 and as it will be illustrated below, is especially useful in the unfolding procedure of this sheath into the body.

10 The surgical action needed to place the present corrective mesh in patients suffering from urinary incontinence is carried out preferably through the vaginal route in local anaesthesia.

A small cut is made under the urethra and with the aid of an instrument generating a suitable space the present mesh is placed inside above the pubis.

15 The mesh is placed without any suture and when in place the said nylon sheath is drawn out and the mesh remains fixed.

Said fins 3, 13, 23 are particularly introduced laterally to urinary bladder neck into Retzius space through "tension-free" techniques by reducing consequently traumas due to the prior art methods which provided for the fixation of lateral  
20 branches of the different prosthesis into Retzius place.

The surgery lasts a few ten minutes then the patient leaves the operating theatre without catheter and can be discharged from the hospital after 24 hours.

Hence the correction of the anatomic defects can be obtained displacing actually the prior art suspension techniques. Practically the mesh 1, 11, 21  
25 substitutes for the function carried out by the collapsed tissue, instead of subjecting it to tensions which can determine further collapses or strength unbalances on the other vaginal segments.

Numerous variations, arrangements, additions, variants or substitutions can be of course made to the embodiments described above in a non limitative and  
30 illustrative way without departing from the scope of the protection of the present invention as it is indicated in the appended claims.

### Claims

1. A corrective mesh for body tissues characterized in that it comprises a main body (2,12, 22) provided with at least a pair of upper lateral fins (3,13, 23) adapted to be introduced along with said main body (2,12, 22) into appropriate body  
5 cavities.
2. A corrective mesh for body tissues according to claim 1, characterized in that said main body (2,12) and said upper lateral fins (3,13) are substantially rectangular shaped with rounded vertexes.
3. A corrective mesh for body tissues according to claim 1, characterized in  
10 that said main body (22) has a generally circular shape with a notch (25) placed near the connection of upper lateral fins (23), said fins (23) being of substantially rectangular shape with rounded vertexes.
4. A corrective mesh for body tissues according to claim 3 characterized in that said notch is rectangular shaped.
- 15 5. A corrective mesh for body tissues according to claim 2 characterized in that said main body (2) has a bulge (4) placed near the connection of said upper lateral fins (3).
6. A Corrective mesh for body tissues according to claim 5 characterized in that said bulge (4) is rectangular shaped.
- 20 7. A corrective mesh for body tissues according to claim 1, characterized in that said mesh (1,11, 21) is made of monofinalment polypropylene.
8. A corrective mesh for body tissues according to claim 1 characterized in that said mesh (1,11, 21) is completely wrapped by a nylon sheath which is removed when the mesh (1,11, 21) has been positioned in the body cavities.
- 25 9. Surgical use of the corrective mesh for body tissues according to one or more claims from 1 to 6 for pathologies concerning female urinary incontinence.
10. Surgical use of the corrective mesh for body tissues according to one or more claims from 1 to 6 for the pathology of prolapse of the rectum.



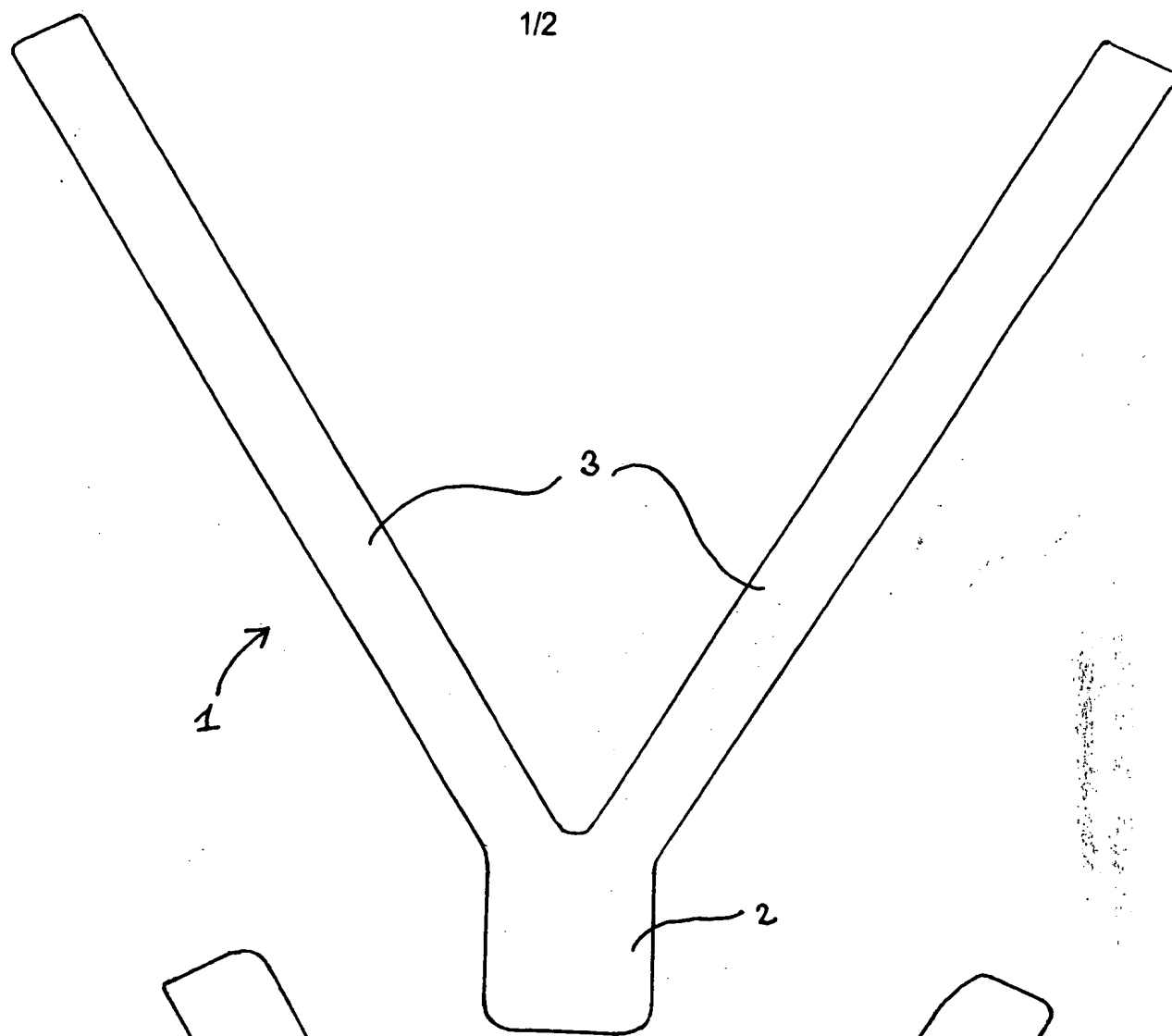


Fig. 1

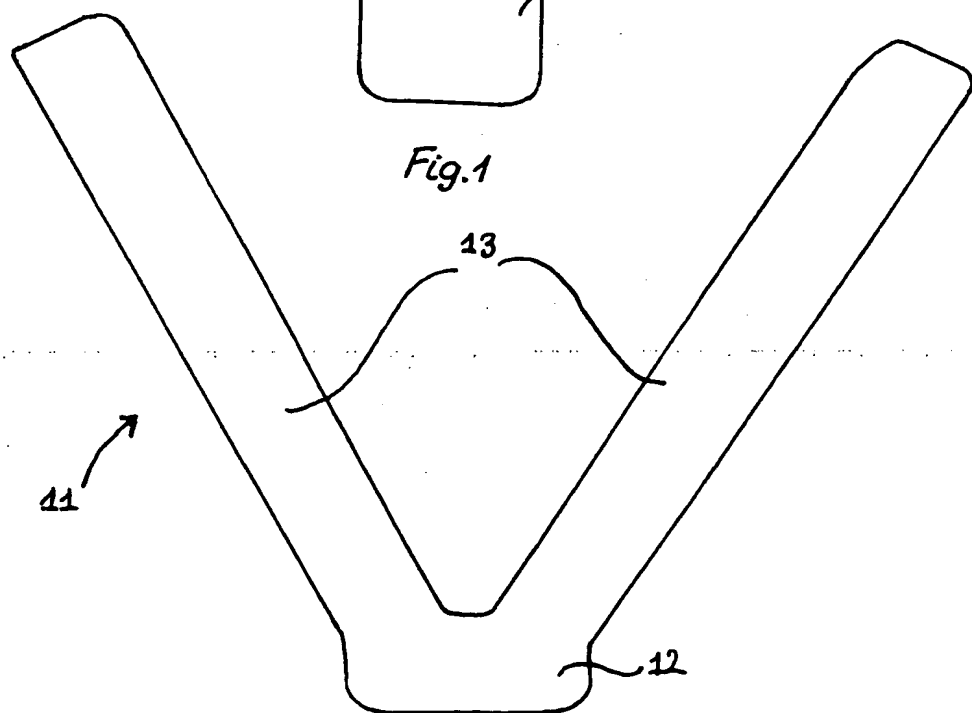


Fig. 4

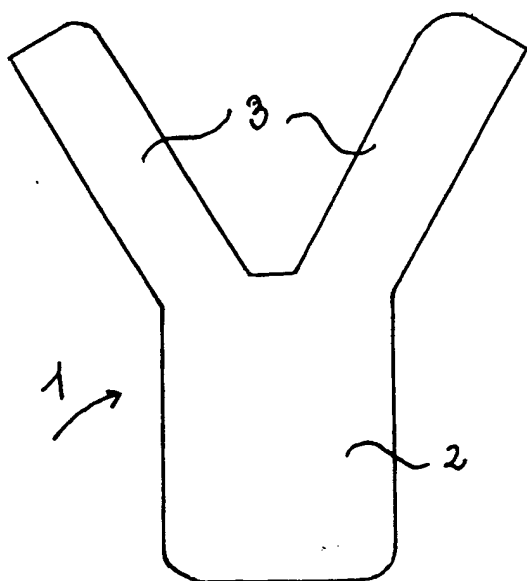


Fig. 2

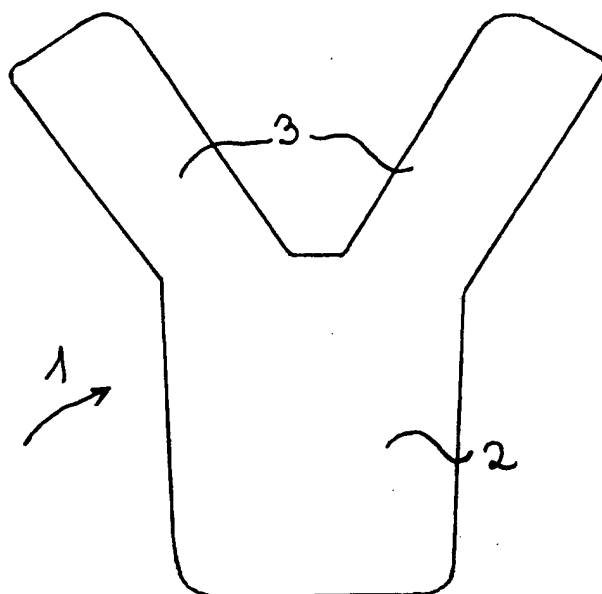


Fig. 3

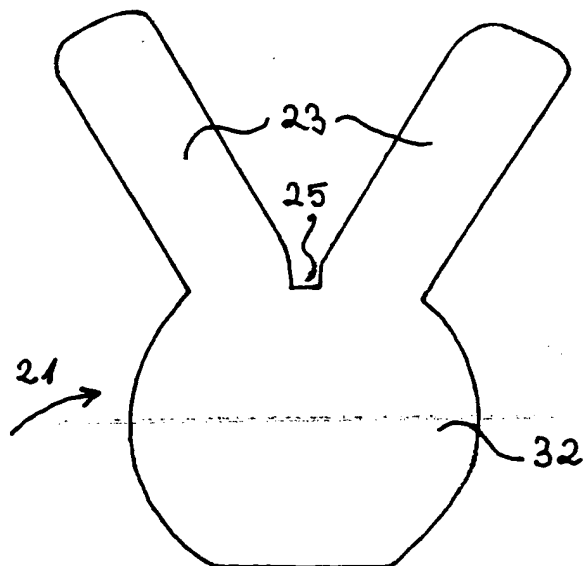


Fig. 5

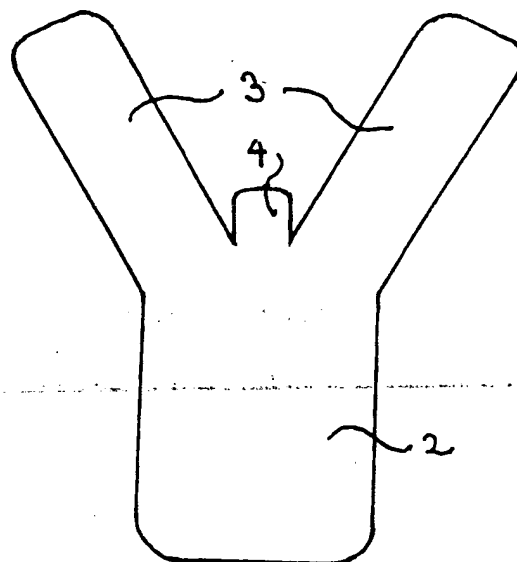


Fig. 6

# INTERNATIONAL SEARCH REPORT

Internat. Application No.

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## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 774 240 A (ETHICON, INC.) 21 May 1997 (1997-05-21) the whole document	1,2,5-7, 9
X	US 5 441 508 A (GAZIELLY ET AL.) 15 August 1995 (1995-08-15) column 3, line 53 -column 4, line 36; figures 5,9	1,2
A	WO 99 16381 A (SCIMED LIFE SYSTEMS, INC.) 8 April 1999 (1999-04-08)	

☐ Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

### \* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
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\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Information on patent family members

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 774240	A	21-05-1997	DE 19544162 C	24-04-1997
			BR 9605581 A	18-08-1998
			CA 2190449 A	18-05-1997
			JP 9201376 A	05-08-1997
			US 5840011 A	24-11-1998
US 5441508	A	15-08-1995	FR 2646343 A	02-11-1990
			AT 111717 T	15-10-1994
			AU 628976 B	24-09-1992
			AU 5567790 A	16-11-1990
			BR 9006729 A	06-08-1991
			CA 2032123 A,C	28-10-1990
			DE 69012730 D	27-10-1994
			DE 69012730 T	11-05-1995
			DK 423297 T	12-12-1994
			EP 0423297 A	24-04-1991
			ES 2063354 T	01-01-1995
			WO 9012551 A	01-11-1990
			JP 2539292 B	02-10-1996
			JP 3505696 T	12-12-1991
			US 5195542 A	23-03-1993
WO 9916381	A	08-04-1999	AU 9512598 A	23-04-1999
			EP 1018980 A	19-07-2000